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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

NIKOLAS CHAPLIN, individually and on
behalf of all others similarly situated,

Plaintiff,

v.

WALMART INC.,

Defendant.

Case No.: 3:23-cv-00878-WHO

**FIRST AMENDED CLASS ACTION
COMPLAINT**

Judge: Honorable William H. Orrick

Complaint filed: January 9, 2023
Trial date: Not yet set

JURY TRIAL DEMANDED

1 Plaintiff Nikolas Chaplin (“Plaintiff”) brings this action against Defendant Walmart Inc.
2 (“Defendant” or “Walmart”), individually and on behalf of all others similarly situated, and alleges
3 upon personal knowledge as to Plaintiff’s acts and experiences, and, as to all other matters, upon
4 information and belief, including investigation conducted by Plaintiff’s attorneys.

5 **NATURE OF THE ACTION**

6 1. This is a consumer protection action that seeks to remedy the unlawful and deceptive,
7 business practices of Defendant with respect to the marketing and sales of its Parent’s Choice Gripe
8 Water products (“Parent’s Choice Gripe Water” or “Product(s)”).

9 2. Defendant distributes, markets, and sells a Product named “Parent’s Choice Gripe
10 Water” as an effective remedy for the symptoms associated with colic in newborn babies and infants.

11 3. Gripe water has been sold to unwitting parents as a treatment for colicky infants for
12 over a century. It is considered a natural “folk” or “alternative” remedy. From a science-based
13 standpoint, “alternative” medicine is a misnomer. When the clinical evidence demonstrates that an
14 intervention is effective, it becomes a part of accepted medicine. Yet many “alternative,” and natural
15 “folk” treatments are sold in the absence of evidence and when the scientific evidence shows
16 otherwise. Defendant takes advantage of this misconception by placing the words “Gripe Water” on
17 the front of the Parent’s Choice Gripe Water packaging.

18 4. None of the ingredients in Parent’s Choice Gripe Water provide relief from stomach
19 discomfort, gassiness, or any of the other symptoms of colic. Scientific studies have found that gripe
20 water is ineffective for treating colic in newborns and may in fact disrupt the digestive system of
21 infants and newborns. No respected medical practitioner recommends the use of herbal remedies or
22 gripe water for use in colicky infants. Defendant is peddling snake oil at the expense of desperate
23 consumers.

24 5. Walmart’s Gripe Water only disrupts a newborn’s/infant’s digestive system. The
25 Product contains sodium bicarbonate which is commonly known as baking soda. Numerous
26 scientific publications warn that the ingredient should not be given to infants because it disrupts the
27 digestive system. In fact, the leading baking soda brand warns “Do not administer to children under
28

1 age 5.” A Product that disrupts a newborn’s/infant’s digestive system cannot effectively treat the
2 symptoms of colic. Reasonable consumers would not have purchased the Product had they known
3 that the Product does not work for its advertised purpose. Defendant knowingly sells the Product
4 despite having actual knowledge that it does not work.

5 6. Throughout the Class Period Defendant manufactured, sold, and distributed Parent’s
6 Choice Gripe Water using a marketing and advertising campaign that it is an effective remedy for
7 the signs and symptoms of colic including stomach discomfort (“discomfort” is euphemism for
8 “pain”).

9 7. Defendant communicates the same substantive colic symptom relief message
10 throughout its advertising and marketing of Parent’s Choice Gripe Water. Accordingly, each
11 consumer who has purchased Parent’s Choice Gripe Water has been exposed to Defendant’s
12 unlawful and misleading advertising.

13 8. As a direct and proximate result of Defendant’s false and misleading advertising
14 claims and marketing practices, Defendant has caused Plaintiff and the members of the Class to
15 purchase a falsely advertised product which does not, and cannot, perform as represented. Plaintiff
16 and other similarly situated consumers have been harmed in the amount they paid for Parent’s
17 Choice Gripe Water.

18 9. Plaintiff brings this action individually, and on behalf of all purchasers of Parent’s
19 Choice Gripe Water products, to halt Defendant’s unlawful sales and marketing of these products
20 and for violations of the California Consumer Legal Remedies Act (“CLRA”), Civil Code §§ 1750,
21 *et seq.*, Unfair Competition Law (“UCL”), Bus. & Prof. Code §§ 17200, *et seq.*, and for unjust
22 enrichment.

23 **JURISDICTION AND VENUE**

24 10. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)
25 because this is a class action in which: (1) there are over 100 members in the proposed class; (2)
26 members of the proposed class have a different citizenship from Defendant; and (3) the claims of
27
28

1 the proposed class members exceed \$5,000,000 in the aggregate, exclusive of interest and costs. *See*
2 ECF No. 1 (Defendant’s Notice of Removal).

3 11. This Court has personal jurisdiction over Defendant because Defendant conducts and
4 transacts business in the State of California, contracts to supply goods within the State of California,
5 and supplies goods within the State of California. Defendant has intentionally availed itself of the
6 markets within California through its advertising, marketing, and sales of Parent’s Choice Gripe
7 Water to consumers, including Plaintiff. Further, Defendant has waived any personal jurisdiction
8 challenge by responding to Plaintiff’s initial complaint.

9 12. Venue is proper in this Court because Defendant is doing business in this County, and
10 Plaintiff purchased Parent’s Choice Gripe Water in this County.

11 **PARTIES**

12 13. Plaintiff Nikolas Chaplin is an individual consumer who, at all times relevant to this
13 action, was a citizen of and resided in California. Before purchasing the Parent’s Choice Gripe
14 Water products, Plaintiff saw Defendant’s representations by reading the label of Parent’s Choice
15 Gripe Water including Defendant’s representations on the packaging that the Product is “Gripe
16 Water” comparable to “Mommy’s Bliss Gripe Water Original.” In reliance on the claims at issue
17 made on the label and on the belief that Parent’s Choice Gripe Water was effective at reducing the
18 symptoms of colic, Plaintiff purchased Parent’s Choice Gripe Water for his child that was suffering
19 from colicky symptoms between approximately 2019 and 2020 at Walmart retail stores in
20 California, including in Alameda County. Relying on the Product’s colic relief representations,
21 Plaintiff paid approximately \$6 for Parent’s Choice Gripe Water. Had Plaintiff known the truth—
22 that the Product has been found to disrupt an infant’s digestive system and thus, does not provide
23 any relief from the symptoms of colic in infants—he would not have purchased the Parent’s Choice
24 Gripe Water. Plaintiff did not receive the benefit of the bargain, because Defendant’s Parent’s
25 Choice Gripe Water does not and cannot improve the symptoms of colic as advertised. By
26 purchasing the falsely advertised product, Plaintiff suffered injury-in-fact and lost money. Plaintiff
27 continues to desire to purchase a colic relief product that actually reduces the symptoms of colic,
28

1 and he would purchase a colic relief product including the Product in the future if it worked as
2 advertised. However, as a result of Defendant's ongoing false and unlawful advertising, Plaintiff
3 will be unable to rely on the advertising when deciding in the future whether to purchase Parent's
4 Choice Gripe Water.

5 14. Plaintiff wants to buy an effective colic-relief product and Walmart markets its
6 Parent's Choice Gripe Water as an effective colic-relief product, so Plaintiff may buy the product
7 in the future as currently formulated and labeled but would again be misled by the labeling and end
8 up purchasing an ineffective product. Plaintiff currently has an infant under the age of one year.
9 Plaintiff cannot rely on the misleading labeling and lack of disclosure of the product's
10 ineffectiveness at treating colic.

11 15. Plaintiff Chaplin never purchased the Product on Walmart.com. Plaintiff was aware
12 of the Mommy's Bliss product when he purchased Walmart's Gripe Water. Just like Walmart's
13 Gripe Water, Mommy's Bliss was also advertised to treat the symptoms of colic.

14 16. Defendant Walmart Inc. is a publicly-traded Delaware corporation, with a principal
15 place of business in Bentonville, Arkansas. Defendant manufactures, markets, and advertises and
16 distributes Parent's Choice Gripe Water products throughout the United States, including in
17 California. Defendant manufactured, marketed, and sold Parent's Choice Gripe Water products
18 during the Class Period. The planning and execution of the advertising, marketing, labeling,
19 packaging, testing, and/or business operations concerning the Parent's Choice Gripe Water were
20 primarily carried out by Defendant.

21 17. Walmart sells the Parent's Choice Gripe Water products under the brand name
22 "Parent's Choice" which is "Walmart's exclusive, private brand that today extends beyond infant
23 formula."¹ Defendant markets itself as a trustworthy manufacturer of the Products: "We offer
24 everything you need from bath time to bed time and every time in between, all with the high quality
25 we know your little one needs."²

27 ¹ <https://www.parentschoicebaby.com/about-parents-choice.aspx> (last visited Nov. 29, 2022)

28 ² <https://www.walmart.com/ip/Parent-s-Choice-Gripe-Water-Unflavored-4-oz/239077181>
(last visited Nov. 29, 2022).

FACTUAL BACKGROUND

18. Defendant's Parent's Choice Gripe Water products are sold nationwide at Walmart retail chains.

19. Gripe water is commonly known as a treatment for infant stomach discomfort and the other symptoms of infantile colic.

20. Dictionary.com defines "gripe water" as "a solution given to infants to relieve colic."³ Similarly, the online Collins Dictionary defines "gripe water" as "a solution given to infants to relieve colic,"⁴ the online MacMillan Dictionary defines "gripe water" as "a medicine for treating babies who have stomach pain,"⁵ and the online Oxford's Learner's Dictionaries defines "gripe water as "medicine that is given to babies when they have stomach pains."⁶

21. The packaging of Parent's Choice Gripe Water is depicted below:

³ <https://www.dictionary.com/browse/gripe-water#:~:text=noun,to%20infants%20to%20relieve%20colic> (last visited Nov. 29, 2022).

⁴ <https://www.collinsdictionary.com/us/dictionary/english/gripe-water> (last visited Nov. 29, 2022).

⁵ <https://www.macmillandictionary.com/us/dictionary/british/gripe-water> (last visited Nov. 29, 2022).

⁶ <https://www.oxfordlearnersdictionaries.com/us/definition/english/gripe-watertm> (last visited Nov. 29, 2022).



22. As shown above, the packaging for Parent's Choice Gripe Water represents that it is Gripe Water, implying that it is an effective remedy for the symptoms of colic. The Products' packaging also refers consumers to Mommy's Bliss Gripe Water which claims that the product "relieves occasional stomach discomfort from Gas, Colic, Fussiness, Hiccups." To further reinforce that the Parent's Choice Gripe Water is an ineffective treatment for the symptoms of colic, Walmart places its Parent's Choice Gripe Water next to the Mommy's Bliss Gripe Water and other gripe water products on the shelves of Walmart retail stores.

23. Defendant also represents that the Parent's Choice Gripe Water is a safe and effective product for infants as young as 2 weeks old. The packaging states that there is a "Recommended Serving" for Infants 2 weeks to 6 months of age:

DIRECTIONS: Shake well. Slowly dispense liquid, toward side of mouth/inner cheek, using the provided dropper or syringe up to 6 times in 24-hour period. We recommend discarding 6 weeks after opening.

RECOMMENDED SERVING:

Infants 2 weeks to 1 month of age:	2.5 mL
Babies 1 to 6 months of age:	5 mL
Children 6 months and older:	10 mL
Adults:	30 mL

24. Defendant's Parent's Choice Gripe Water contains the following ingredients: "ORGANIC GINGER EXTRACT, ORGANIC FENNEL EXTRACT, PURIFIED WATER, VEGETABLE GLYCERIN, SODIUM BICARBONATE, CITRUS SIGFLAVONOID EXTRACT, CITRIC ACID, POTASSIUM SORBATE."⁷

25. Defendant's website provides evidence of the Product's intended use and the implied labeling claims. The Website advertisements are merely extrinsic evidence for the reasonable consumer standard, to contextualize how a reasonable consumer would understand the gripe water label. The Website advertisements are also evidence of the Product's implied disease claims (see below) and are admissible under the Federal Food, Drug, and Cosmetic Act to show the intended use of the Product.

26. On its website, Walmart represents the following directly below the Parent's Choice Gripe Water product images: "Help relieve your baby's upset tummy with Parent's Choice Original Gripe Water, 2 Weeks+. This herbal supplement solution helps treat gassiness and stomach discomfort. ... Discomfort in your little ones stomach can be frustrating and upsetting, but it's simple to treat."

About this item

Product details

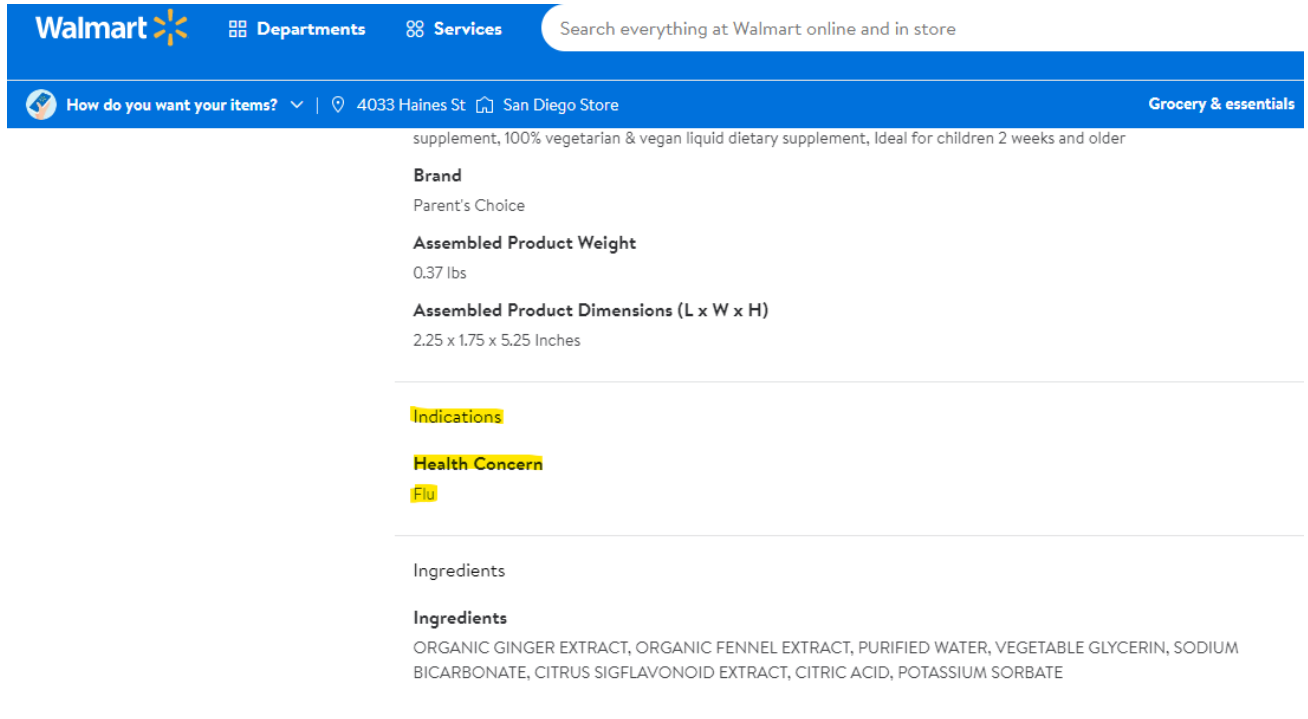
Herbal Supplement with Organic Ginger & Fennel Extracts, 4oz

Help relieve your baby's upset tummy with Parent's Choice Original Gripe Water, 2 Weeks+. This herbal supplement solution helps treat gassiness and stomach discomfort. Our 4-fluid ounce package is convenient for storing in your medicine cabinet or packing in a baby bag for on-the-go use. Discomfort in your little ones stomach can be frustrating and upsetting, but it's simple to treat. All you need to do is slowly dispense the liquid grip water towards the side of your child's inner cheek, using the provided dropper or syringe up to 6 times in a 24-hour period. Your baby will be back to their happy and playful self in no time.

Parent's Choice provides parents with baby and toddler products you need at a price that won't push your budget over the edge. We offer everything you need from bath time to bed time and every time in between, all with the high quality we know your little one needs.

(the “Website Claims”). A printout of Defendant’s website as of November 30, 2022, is attached hereto as **Exhibit 1**.

27. Defendant’s website also states that Parent’s Choice Gripe Water will treat the flu. These advertising statements are highlighted below:⁸



28. The labeling and Website Claims violate federal and state law because they imply, as Walmart intends, that the Products are capable of treating the symptoms of disease. The FDA considers colic relief claims to be disease claims which require premarket drug approval. On its Website, Walmart admits that “similar items” to the Parent’s Choice Gripe Water are FDA approved medications such as Parent’s Choice Baby Cough Syrup and Parent’s Choice Infant Pain & Fever Acetaminophen:⁹

⁸ <https://www.walmart.com/ip/Parent-s-Choice-Gripe-Water-Unflavored-4-oz/239077181> (screen shot taken on Nov. 22, 2022)

⁹ <https://www.walmart.com/ip/Parent-s-Choice-Gripe-Water-Unflavored-4-oz/239077181> (screen shot taken on Nov. 22, 2022)

Similar items you might like

Based on what customers bought

100+ bought since yesterday



+ Add

\$5.12 \$2.56/fl oz

Parent's Choice Baby Cough Syrup, 2 fl. oz.

★★★★☆ 12

Pickup Delivery

2-day shipping

100+ bought since yesterday



+ Add

Sponsored

\$10.12 \$2.02/fl oz

Xyzal Children's Allergy 24HR Oral Solution (5 Oz),...

★★★★★ 157

Pickup Delivery

1-day shipping

100+ bought since yesterday



+ Add

Sponsored

\$7.97 \$1.99/fl oz

Genexa Children's Acetaminophen Oral Suspension, 4 oz

★★★★☆ 3081

Pickup Delivery

3+ day shipping

500+ bought since yesterday



+ Add

\$3.94 \$1.97/fl oz

Parent's Choice Infants' Pain and Fever, Dye-Free, Grape, 2 Fl...

★★★★★ 45

Pickup Delivery

3+ day shipping

29. The ingredients in Parent's Choice Gripe Water have been shown to not provide relief from the symptoms of colic in infants including stomach discomfort.¹⁰ The scientific community ***recommends against*** the use of gripe water in children and does not recommend any of the ingredients in Parent's Choice Gripe Water for use in colicky infants because they do not work. The ingredients in Parent's Choice Gripe Water are not effective at providing any of the advertised benefits. Further, Defendant does not disclose that the sodium bicarbonate in the Products disrupts a newborn's/infant's digestive system, and thus, does not help with the symptoms of colic.

¹⁰ Divya Jacob, *Why Is Gripe Water Banned?* MedicineNet available at https://www.medicinenet.com/why_is_gripe_water_banned/article.htm (last visited Nov. 9, 2022).

DEFENDANT’S FALSE, MISLEADING, AND UNLAWFUL ADVERTISING

Defendant’s False and Misleading Advertising: Sodium Bicarbonate Is Proven Ineffective Because It Can Only Disrupt a Newborn’s/infant’s Digestive System

30. The Parent’s Choice Gripe Water products contain sodium bicarbonate which is more commonly known as baking soda.

31. Material Safety Data Sheets state that sodium bicarbonate disrupts a newborn’s/infant’s digestive system: “May be harmful if swallowed.” “Harmful if swallowed,” and “IF SWALLOWED” “Immediately call poison center or doctor. DO NOT induce vomiting.”¹¹ The “Potential Health Effects” of sodium bicarbonate include “Causes gastrointestinal tract irritation.”¹²

32. The National Capital Poison Center states that use of “baking soda as a homemade antacid can cause rapid formation of gas in the stomach. You should not use baking soda to treat stomach upset without specific direction from your healthcare provider. Stomach ruptures can occur with baking soda use after alcohol bingeing or a large meal. For these reasons, it is better to use over-the-counter antacid products such as calcium carbonate (like Tums®), which work in a similar way but are much safer.”¹³ It also states that if baking soda is swallowed, Poison Control should be called.

33. The leading baking soda brand, Arm & Hammer, states on the packaging “Do not administer to children under age 5” and “KEEP OUT OF REACH OF CHILDREN If swallowed, get medical help or contact a Poison Control Center right away.”¹⁴

34. Numerous published reports have found that sodium bicarbonate disrupts a newborn’s/infant’s digestive system and does not help with the symptoms of colic. An infant developed proteinuria (high levels of protein in urine) caused by the addition of sodium bicarbonate

¹¹ See https://files.dep.state.pa.us/OilGas/BOGM/BOGMPortalFiles/IndustryResources/InformationalResources/HDD_Safety_Data_Sheets/Sodium_Bicarbonate_SDS.pdf.

¹² <https://fscimage.fishersci.com/msds/20970.htm> (last visited Nov. 30, 2022).

¹³ <https://www.poison.org/articles/baking-soda> (last visited Nov. 30, 2022).

¹⁴ <https://fda.report/DailyMed/b70f52eb-e3a6-4b08-b38b-8855f736ed65> (last visited Nov. 30, 2022)

1 to infant formula.¹⁵ In a report titled *Baking soda: a potentially fatal home remedy*, an infant was
 2 administered baking soda to “help the baby burp.” The authors reported that an infant developed
 3 “life-threatening complication” after consuming sodium bicarbonate and concluded that several
 4 case reports have been published which “emphasizes the need for warnings on baking soda
 5 products.”¹⁶

6 35. Al-abri and Kearny (2014) conducted a retrospective systematic review of all
 7 symptomatic cases from 2000 to 2012 involving sodium bicarbonate. One hundred ninety-two cases
 8 were identified. The authors concluded that the “baking soda can result in serious electrolyte and
 9 acid/base imbalances.”¹⁷ The study also noted that since 1990 the printed instructions for the leading
 10 baking soda product “were modified to advise against administering the product to children under
 11 age 5 years, because of reported seizure and respiratory depression in children.” In one case, a dose
 12 of 1-3 tbs of baking soda was shown to be completely ineffective at treating colic as it was associated
 13 with a death of a child and was reported by the National Poison Data System. In several cases, the
 14 use of baking soda was reported to be ineffective at treating colic because it caused significant
 15 electrolyte and acid-base abnormalities including alkalosis, hypernatremia, hypokalemia,
 16 hypochloremia and hypocalcaemia. The authors issued a stern warning to not use baking soda in
 17 infants and newborns: “healthcare providers should warn parents against using baking soda as an
 18 antacid in younger children. We also found further evidence that use of baking soda in children may
 19 be a common practice by the public after reviewing and noting several information calls to the
 20 California Poison Control System regarding from parents contemplating its use for their children.”

21 36. Even Walmart’s gripe water competitors explain that sodium bicarbonate causes an
 22 imbalance in an infant’s electrolytes:

23 Sodium Bicarbonate (a.k.a. Baking Soda). Sodium bicarbonate is an alkali (antacid)
 24 which alters the naturally occurring pH of a baby’s stomach acid. It may counteract

25
 26 ¹⁵ Wechsler D et al. Apparent Proteinuria as a Consequence of Sodium Bicarbonate
 Ingestion. *Pediatrics*. 1990;86(2):318-319.

27 ¹⁶ Nichols MH et al. Baking Soda: a potentially fatal home remedy. *Pediatr Emerg Care*.
 1995;11(2):109-111.

28 ¹⁷ Al-Abri SA, Kearney T. Baking soda misuse as a home remedy: case experience of the
 California Poison Control System. *J Clin Pharm Ther*. 2014 Feb;39(1):73-7.

some discomfort caused by natural acidity in a baby's tummy. However, stomach acid serves a useful purpose because it helps the body digest food and protects the gut from infections. Disrupting the stomach's natural acidity has led to concerns about risk for infection and malabsorption of nutrients like calcium, magnesium, B12, and iron. For this reason, sodium bicarbonate-containing products are not to be consumed by "children under 5 years of age", as stated clearly on antacid and baking soda boxes. Antacids always warn against extended use: "Do not use for more than 2 weeks." According to some doctors, sodium bicarbonate can cause an imbalance in babies' electrolytes, which can also lead to serious problems. Please note that antacids do interact with or prevent the absorption of many medications. According to Medline Plus, a service of the National Library of Medicine, antacids (e.g. sodium bicarbonate) "should not be given to young children (up to 6 years of age) unless prescribed by their doctor." Since children often cannot describe their symptoms well, doctor visits are advisable before giving any antacids to children. The condition may require other treatment. In such cases, not only will antacids not help, they may actually lead to unwanted side effects and/ or worsening of condition. Medline also warns against taking large doses of sodium bicarbonate with large amounts of milk or milk products. To do so may increase the chance of side effects.¹⁸

37. Medical News Today states that "a parent or caregiver should not give baking soda or any medications containing sodium bicarbonate to a child" because it does not work—"is not safe."¹⁹

38. Drs. Brown, Whaley, and Arnold published an article titled "Acute Bicarbonate Intoxication from a Folk Remedy." An infant that was in good health was given sodium bicarbonate as a cold remedy which resulted in hypernatremia, an acute metabolic alkalosis, and apnea—that is, it did not work. The authors issued a public warning that baking soda disrupts a newborn's/infant's digestive system: "The use in infants of home remedies containing bicarbonate should be discouraged."²⁰

39. An article published in *Emergency Nurse* similarly found that sodium bicarbonate disrupts a newborn's/infant's digestive system as it "can cause hypernatraemia and other metabolic disturbances."²¹ The article noted that "poisoning has occurred after use of sodium bicarbonate as

¹⁸

https://www.coliccalm.com/baby_infant_newborn_articles/baby_colic_treatment.htm#SodiumBicarb (last visited Nov. 30, 2022).

¹⁹ <https://www.medicalnewstoday.com/articles/dangers-of-drinking-baking-soda#benefits> (last visited Nov. 30, 2022).

²⁰ Brown A.L. et al. Acute Bicarbonate Intoxication From a Folk Remedy. *Am. J. Dis. Child.* 1981;135:965.

²¹ Bates N. Poisoning: Sodium Chloride and sodium bicarbonate. *Emergency Nurse.* 2003;11(2):33-37.

1 a remedy for gastrointestinal” symptoms in infants.

2 40. Defendant’s Parent’s Choice Gripe Water disrupts a newborn’s/infant’s digestive
3 system. Despite this evidence, Defendant promotes the use of the Product as a treatment for infants
4 as young as two weeks old. Defendant does not disclose that its Gripe Water does not work because
5 it disrupts a newborn’s/infant’s digestive system.

6 ***Defendant’s False and Misleading Advertising: Walmart’s Gripe Water is Shown to Be***
7 ***Ineffective at Treating the Symptoms of Colic in Newborns & Infants***
8

9 41. Gripe water products were originally developed to treat the symptoms of malaria
10 during the 1800s and originally contained a mixture of baking soda, alcohol, and herbs. Gripe water
11 was thought to help calm a fussy baby. However, any perceived benefit was due to the presence of
12 alcohol. Modern formulations of gripe water do not contain alcohol and often do not contain baking
13 soda. However, that does not stop companies, like Defendant, from seeking to capitalize from name
14 recognition of gripe water.

15 42. Infants do not need or require the ingredients in Parent’s Choice Gripe Water. There
16 is no required daily intake for any of the ingredients in Parent’s Choice Gripe Water—the Centers
17 for Disease Control and Prevention (CDC) states that a child only needs essential vitamins and
18 minerals such as Vitamin D, iron, and zinc to grow healthy and strong.²² An infant’s digestive
19 system does not need any of the ingredients in Parent’s Choice Gripe Water because the digestive
20 system maintains homeostasis on its own along with the breast milk/formula consumed.
21 Consequently, if a substance such as Parent’s Choice Gripe Water disrupted this homeostasis,
22 disease and/or increased bacteria, allergies, and intestinal irritation would result.

23 43. The scientific community has advised against the use of gripe water for good reason—
24 “newborn infants should not be given food or drink other than breast milk, unless medically
25 indicated.”²³

26
27 ²² See <https://www.cdc.gov/nutrition/infantandtoddlernutrition/vitamins-minerals/index.html>
(last visited Nov. 18, 2022).

28 ²³ Adhisivam B. Is gripe water baby-friendly? J. Pharmacol. Pharmacother. 212
Apr;3(2):207-8.

44. The scientific community cautions that use of gripe water products like Parent's Choice Gripe Water is an "irrational practice" which increases the risk of increased bacteria, allergies, and intestinal irritation.²⁴ Health Link, a health information service in Canada, also warns new parents: "Do not use unapproved, unproven, or potentially dangerous substances or methods as treatment for your baby who has colic."²⁵ The World Health Organization specifically recommends that mothers should exclusively breastfeed infants for optimal health.²⁶ The Canadian Paediatric Society likewise warns "Talk to your doctor before using over-the-counter or 'natural' products for colic. There is very little scientific evidence to show that these products help."²⁷

45. Accordingly, the scientific community has stated that gripe water advertising "need[s] to be curbed and we should ensure that no promotion for infant foods or drinks other than breast milk is done ... doctors should stop prescribing these ... medications and laws should be made stringent to prevent over the counter access of the same."²⁸

46. Evidence-based professional and national recommendations for the treatment of infant gastrointestinal issues recommend against the use of gripe water, herbal supplements, or any of the ingredients in Parent's Choice Gripe Water.

47. The American Academy of Family Physicians (AAFP) does not recommend the use of gripe water and herbal supplements including herbal ingredients such as fennel, chamomile, lemon balm.²⁹ The AAFP warns that the use of herbal products should not be administered as a treatment for infantile colic: "parents should be cautioned about their use."³⁰ The AAFP also notes that use of herbal products can create a "potential interference with normal feeding."

²⁴ *Id.*

²⁵ <https://www.healthlinkbc.ca/pregnancy-parenting/parenting-babies-0-12-months/baby-health/colic-harmful-treatments> (last visited Nov. 30, 2022).

²⁶ Vallenias C, Savage F. *Evidence for the ten steps to successful breastfeeding*. Geneva: World Health Organization/CHD/98.9; 1998. pp. 48–61.

²⁷ https://caringforkids.cps.ca/handouts/pregnancy-and-babies/colic_and_crying (last visited Nov. 9, 2022)

²⁸ Adhisivam B. Is gripe water baby-friendly? *J. Pharmacol. Pharmacother.* 2012 Apr;3(2):207-8.

²⁹ Johnson J.D. et al. Infantile colic: recognition and treatment. *American Family Physician.* 2015;92(7):577-582.

³⁰ Roberts D.M. et al. Infantile Colic. *American Family Physician.* 2004;70(4):735-740.

48. Ellwood et al. (2020) performed a systematic review of the available guidelines for the treatment of infantile colic which was published in the *British Medical Journal*.³¹ The aim of the study was to compare meta-data from different systematic review and national treatments guidelines for infantile colic on common outcomes. The authors specifically assessed the effectiveness of several treatment modalities on colic symptoms including infant crying time, sleep distress and adverse events. The authors note the herbal mixtures “may be harmful because herbal mixtures may affect optimal milk consumption.” The analysis found that “herbal supplements (e.g., fennel)” are “non-recommended interventions” by The National Institute for Health and Care Excellence (NICE) on two separate occasions (2015 and 2017). Similarly, gripe water products were reported as a “non-recommended intervention” by American Academy of Family Physicians.

49. The National Institutes of Health (NIH) “Colic and crying – self-care” guide does not recommend the use of gripe water or any other herbal supplements.³² Instead, the NIH recommends several techniques to comfort and calm an infant.

50. The National Health Service (NHS), the publicly funded healthcare system in England, recently published evidence-based treatment guidelines titled *Managing Colic in Infants Pathway*.³³ The NHS has a “Do not recommend” rating for herbal supplements like Parent’s Choice Gripe Water.

51. The Royal Children’s Hospital (RCH) published evidence-based clinical practice guidelines for unsettled or crying babies in 2019. The guideline has been endorsed by the Paediatric Improvement Collaborative and specifically does not recommend “colic mixtures (e.g., gripe water) – no proven benefit.”³⁴

52. The British Journal of Family Medicine (BJFM) has published treatment guidelines for infantile colic. The BJFM guidelines “do not support the[] use” of herbal remedies.³⁵

³¹ Ellwood J. et al. Comparison of common interventions for the treatment of infantile colic: a systematic review of reviews and guidelines. *BMJ Open*. 2020;10e035405.

³² See MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US) available at <https://medlineplus.gov/ency/patientinstructions/000753.htm> (last visited Nov. 9, 2022).

³³ NHS. *Managing Colic in Infants Pathway* (September 2022).

³⁴ https://www.rch.org.au/clinicalguide/guideline_index/Crying_Baby_Infant_Distress/ (last visited Nov. 9, 2022).

³⁵ Wall A. and Bogle V. Spotlight: infantile colic. *BJFM*. 2018;6(4).

53. Mount Sinai's Health Library warns "DO NOT give ginger to children under 2."³⁶ For fennel (*Foeniculum vulgare*), Mount Sinai states "DO NOT give these herbs to your child on your own."³⁷

54. Biagioli and colleagues published a systematic review to assess the effectiveness and safety of agents for reducing colic in infants younger than four months of age. The authors utilized the standard methodological procedures of The Cochrane Collaboration. The "Authors conclusions" were "available evidence shows that herbal agents, sugar, ... cannot be recommended for infants with colic."³⁸

55. In 2019, peer-reviewed treatment guidelines were published which found that "Herbal remedies should not be given as there are potential risks of side effects, which may interfere with the infant's feeding."³⁹ Instead, the guidelines recommend parental reassurance and an allergen-restricted diet for mothers with a history of food intolerance or allergies.

56. Zhang et al. (2015) conducted a comprehensive study using data from the Infant Feeding Practices Study II, a longitudinal survey of women studied from pregnancy through the infant's first year. This was the first study to examine the prevalence of dietary botanical supplement use among US infants. The authors concluded that "many supplements and teas used were marketed and sold specifically for infants" and warn others that "supplements given to infants may pose health risks, health care providers need to recognize that infants under their care may be receiving supplements or teas."⁴⁰

57. Jain et al. (2015)⁴¹ published a cross-sectional study examining 335 mothers of infants. The authors concluded that gripe water "administration is a common problem in infants and

³⁶ <https://www.mountsinai.org/health-library/herb/ginger> (last visited No. 29, 2022).

³⁷ <https://www.mountsinai.org/health-library/condition/infantile-colic> (last visited No. 29, 2022).

³⁸ Biagioli E, Tarasco V, Lingua C, Moja L, Savino F. Pain-relieving agents for infantile colic. Cochrane Database of Systematic Reviews 2016;9(CD009999).

³⁹ Lam T.M.L et al. Approach to infantile colic in primary care. Singapore Med J. 2019;60(1):12-16.

⁴⁰ Zhang Y. et al. Feeding of Dietary Botanical Supplements and Teas to Infants in the United States. Pediatrics. 2015;127(6):1060-1066.

⁴¹ Jain K. et al. Gripe water administration in Infants 1-6 months of age - a cross-sectional study. Clin Diagn Res. 2015 Nov;9(11):SC06-8.

1 remains a significant challenge that thwarts exclusive breast feeding.” The authors also commented
 2 that gripe water does not prevent infantile colic and may be associated with vomiting and
 3 constipation.

4 58. Gutiérrez-Castrellón et al. (2017) performed a systematic review and network meta-
 5 analysis of clinical trials published between 1960 and 2015 for the treatment of infantile colic.
 6 Pooled interventions included in the network meta-analysis were herbal remedies, including the
 7 ingredients found in Parent’s Choice Gripe Water. The authors reported wide confidence intervals
 8 in the results with considerable heterogeneity which crossed the line of no effect. In conclusion, the
 9 authors did not recommend herbal medicine, including ingredients in Parent’s Choice Gripe Water,
 10 for colic.⁴²

11 59. Defendant’s Parent’s Choice Gripe Water does not relieve colic or the signs and
 12 symptoms of colic including gassiness and stomach discomfort in newborns or infants. A significant
 13 portion of reasonable targeted customers and the reasonable general consuming public are misled
 14 by the Product’s label.

15 ***Defendant’s Gripe Water Implied Disease Claims***

16 60. Defendant’s labeling of the Product includes implied claims that it is intended to treat
 17 the symptoms of infantile colic, including gassiness and stomach discomfort. The FDA has stated
 18 that these types of advertising claims violate federal regulations which also violate state law.⁴³

19 61. The FDA recognizes that products marketed as supplements may implicitly claim to
 20 impact a disease or the signs of symptoms of a disease. 65 Fed. Reg. 1000 (Jan. 6, 2000) (codified
 21 at 21 C.F.R. pt. 101) at 1012. Implied disease claims do not mention the name of a specific disease
 22 but refer to identifiable characteristics of a disease from which the disease itself may be inferred.
 23 *Id.* In determining whether a product is implying disease treatment or prevention, regulatory
 24

25 ⁴² Gutiérrez-Castrellón P, Indrio F, Bolio-Galvis A, et al. Efficacy of *Lactobacillus reuteri*
 26 DSM 17938 for infantile colic. Systematic review with network meta-analysis. *Medicine*.
 2017;96(51).

27 ⁴³ The FDA regulations at issue are incorporated into California law through the Sherman
 28 Food, Drug, and Cosmetic Law (“Sherman Law”). Health & Saf. Code § 110100. In addition to
 this blanket provision, the Sherman Law adopts the regulatory provisions at issue here. *See id.* at
 §§ 109925, 111550.

1 authorities and courts look for other evidence of intended use. 65 Fed. Reg. at 1006. This includes
 2 other advertisements such as the Website Claims, marketing studies and surveys, and Walmart’s
 3 intended target audience. Any “extra-label material” can be considered in determining whether a
 4 Product is intended to be used as disease treatment or prevention. “District courts within this circuit
 5 have considered factors such as the product's advertisements, the consumer's experience with the
 6 product, and market research showing consumer's typical uses of the product.” *Kroessler v. CVS*
 7 *Health Corp.*, 977 F.3d 803, 815 n.9 (9th Cir. 2020)

8 62. Walmart’s Gripe Water is alleged to be an unapproved drug under the FDCA and
 9 California’s Sherman Law, because it is advertised with implied claims that it is intended to treat
 10 the symptoms of infantile colic, including gassiness and stomach discomfort. This violates 21
 11 U.S.C. §§ 343(r)(6), 21 C.F.R §101.93(g)(2), and Cal. Health & Saf. Code §§ 110100, 111550. To
 12 determine where a statement is an implied disease claim, the FDA first looks to the “actual label on
 13 the supplement” and then looks to “extra-label material.” Here, the Website Claims reveal
 14 Walmart’s intended message of its “Gripe Water” and “Compare to Mommy’s Bliss” labeling
 15 message—that the product is intended to treat the symptoms of colic.

16 63. 21 U.S.C. § 343(r)(6) states that a dietary supplement “may not claim to diagnose,
 17 mitigate, treat, cure, or prevent a specific disease or class of diseases.” To be a dietary supplement
 18 that claims to have an effect on the function of the body (here, colic symptom relief), the Product
 19 must have the FDA disclaimer “This statement has not been evaluated by the Food and Drug
 20 Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”
 21 Defendant does not print this statement on its label. To be a dietary supplement, the Product that
 22 claims to have an effect on the function of the body (here, colic symptom relief), “the manufacturer
 23 shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement
 24 with such statement that such a statement is being made.” Defendant never sent this notification.
 25 These facts alone make Defendant’s Gripe Water an illegal product. These facts show that the
 26 Product is not a “food” and is not shielded by any GRAS status (see also below).

64. 21 C.F.R §101.93(g)(2) states that a dietary supplement cannot “impl[y] disease prevention or treatment.” Under 21 C.F.R §101.93(g)(2), a dietary supplement cannot “implicitly” claim to “diagnose, mitigate, treat, cure, or prevent disease,” or “implicitly” claim to have “an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology.” As described herein, the FDA and courts look at all extra-label evidence to determine whether a Product is intended to treat or prevent disease symptoms.

65. Advertising which implies a product has “an effect on the characteristic signs or symptoms” of a disease is considered a drug which requires FDA pre-market approval. 21 CFR 101.93. Implication that a product can treat a disease’s “characteristic signs or symptoms” (without referring to the disease itself) is an unlawful disease claim. *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 809 (9th Cir. 2020). “The name of the product” can imply disease prevention/treatment. 21 C.F.R. § 101.93(g)(2)(iv)(A).

66. Here, Walmart’s Gripe Water is intended to treat the signs and symptoms of colic which are the symptoms of disease according to the FDA. The FDA has stated a product that implies “colic relief” or “helps soothe fussiness and crying in colicky babies” “is intended for use as drug within the meaning of 21 U.S.C. 321(g)(1)(B)” and requires premarket drug status approval. (see below and **Exhibits 3-6** attached).

67. Infantile colic refers to a widespread clinical disease condition in infants that causes inconsolable crying, fussing, hiccups, stomach discomfort, and irritability. These symptoms range from being benign to life-threatening.⁴⁴ The only proven treatment of colic is dicyclomine hydrochloride, an anticholinergic drug. Because there is a “drug” for treating colic, Walmart’s Gripe Water is can also considered to be a drug as it is intended to treat and prevent the same symptoms as an approved drug. This has not stopped companies like Defendant from exploiting struggling parents seeking to calm their newborns exhibiting prolonged periods of distress.

68. Defendant’s Gripe Water is the perfect scam because infantile colic typically subsides by the age of 4-5 months. Thus, consumers using Walmart’s Gripe Water may incorrectly think the

⁴⁴ Savino F & Tarasco V, New treatments for infant colic. *Current Opinion in Pediatrics*. 2010;22:000-000.

1 Gripe Water had an effect on the colic symptoms although it has done nothing to actually help the
2 infant's symptoms, and, in fact, makes them worse.

3 69. Infantile colic is known to have a significant impact on infants and their families.
4 Defendant takes advantage of these desperate parents by unlawfully advertising its Parent's Choice
5 Gripe Water as a treatment for colic and its symptoms. The FDA has publicly warned that claims
6 of colic relief classify the product as an unapproved drug which may result in fines, up to one year
7 in jail, a permanent or temporary injunction, or seizure. *See* 21 U.S.C. §§ 332-334.

8 70. The Product's packaging states that it is "Gripe Water." Defendant uses the term
9 "Gripe Water" because it is a well-known name for products that are intended to treat the symptoms
10 of infantile colic and implies that the Product can treat stomach discomfort, gassiness, and the other
11 symptoms of infantile colic. The Product's packaging also states "COMPARE TO MOMMY'S
12 BLISS® GRIPE WATER." The labeling of the Mommy's Bliss Gripe Water products states that it
13 "relieves occasional stomach discomfort from Gas, Colic, Fussiness, Hiccups." To further reinforce
14 that the Parent's Choice Gripe Water is an effective treatment for the symptoms of colic, Defendant
15 places its Parent's Choice Gripe Water next to the Mommy's Bliss Gripe Water and other gripe
16 water products on the shelves of Walmart retail stores. The Website Claims accompany the
17 packaging and form a textual relationship with the Parent's Choice Gripe Water labeling. The
18 Website Claims state that the Product will "relieve you baby's upset tummy," that it is for ages "2
19 Weeks+," that it "helps treat gassiness and stomach discomfort," that the Product can be stored "in
20 your medicine cabinet," and that "discomfort in your little ones stomach can be frustrating and
21 upsetting, but it's simple to treat. All you need to do is slowly dispense the liquid grip water towards
22 the side of your child's inner cheek, using the provided dropper or syringe up to 6 times in a 24-hour
23 period. Your baby will be back to their happy and playful self in no time." The Website Claims
24 reveal that Walmart intends that its Gripe Water be used to treat the signs and symptoms of disease
25 as the Website Claims state the Product's "Indications" and "Health Concern" is the "flu."
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1 71. In April 2020, the FDA stated that an advertising claim of “Colic Relief” is a claim
2 that the product is intended for use as a drug and directed the company to contact the FDA’s Center
3 for Drug Evaluation and Research.⁴⁵ (highlighted in **Exhibit 3**).

4 72. In June 2021, the FDA stated that a product advertised as “Helps soothe fussiness and
5 crying in colicky babies” and “to reduce fussiness (crying) associated with colic” were unapproved
6 drug claims because “a number of colicky infants have serious medical conditions[.]”⁴⁶ (highlighted
7 in **Exhibit 4**).

8 73. In March 2018, the FDA found that a “Gripe Water” product advertised as “May aid
9 on occasion your baby’s problems with . . . cramping . . .” established that the product was a drug
10 under 21 U.S.C. § 321(g)(1)(B) because it was “intended for use in the cure, mitigation, treatment,
11 or prevention of disease. . . introducing or delivering these products for introduction into interstate
12 commerce for such uses violates the Act.”⁴⁷ (highlighted in **Exhibit 5** at pages 5-6).

13 74. On March 19, 2021, the FDA found that a “Gripe Water” product which was
14 advertised on a promotional website with claims that the Gripe Water product “Gives instant relief
15 to infants and babies ... due to gripe,” “Relieve stomach pain caused by acidity and indigestion” and
16 “Gentle antacid...” was an unapproved new drug.⁴⁸ (highlighted in **Exhibit 6**).

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21 ⁴⁵ FDA Warning Letter to Proctor & Gamble Company, dated April 10, 2020, available via
22 search function at [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)
investigations/compliance-actions-and-activities/warning-letters.

23 ⁴⁶ FDA Warning Letter to SmartyPants Vitamins, dated June 28, 2021, available via search
24 function at [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)
investigations/compliance-actions-and-activities/warning-letters.

25 ⁴⁷ FDA Warning Letter to Ozark Country Herbs, dated March 30, 2018, available at
26 [https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozark-country-herbs-542508-03302018)
letters/ozark-country-herbs-542508-03302018 (last visited Nov. 9, 2022).

27 ⁴⁸ **Exhibit 6** is a notice printed from
28 https://www.accessdata.fda.gov/cms_ia/importalert_190.html (last visited Nov. 29, 2022) which is
an FDA website which contains a compilation of a list of imported unapproved drugs. As a
website printout consists of hundred of pages, Plaintiff provides only the relevant portions in
Exhibit 6.

75. Similarly, Kaiser Permanente’s health encyclopedia states that gripe water is a “potentially dangerous treatment” for colic and that “companies sell gripe water in the United States as a dietary supplement, instead of a medicine, bypassing FDA regulation.”⁴⁹

76. Defendant did not provide the required Parent’s Choice Gripe Water advertising to the FDA within the 30-day period which is required by federal law. I search for the Product on regulations.gov returned no results. Further, there is no FDA disclaimer on the labeling which is required by federal law.

Plaintiff’s Allegations Are Not Preempted

77. Defendant’s advertising constitutes violations of federal and state law. These allegations are not preempted because they do not seek to impose labeling “that is not identical to the requirement of section 343(r).” 21 U.S.C. § 343-1(a)(5).

78. Plaintiff’s unlawful implied disease allegations are not preempted because they are consistent with FDCA regulations. *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 817 (9th Cir. 2020). Plaintiff’s allegations that the Product can disrupt the digestive system of a newborn/infant is not a claim that the product is dangerous or unsafe. This allegation merely supports the allegation that the Product is not effective at relieving colic symptoms.

79. The FDA states that baking soda is “generally recognized as safe” (“GRAS”) as a food ingredient. Plaintiff is not alleging that the Product is harmful or unsafe. Plaintiff alleges the Product is ineffective because it disrupts the digestive system of a newborn/infant. GRAS laws do not state baking soda is an effective remedy for newborn’s/infant’s experiencing the symptoms of colic.

80. GRAS status also does not apply if the if the Product that contains baking soda is labeled or advertised in such a way that the labeling or advertising “may lead to deception of the consumer” or if the labeling or advertising (including any implied claims) violates the Federal Food, Drug, and Cosmetic Act (“FDCA”). 21 C.F.R. § 184.1(c).

⁴⁹ <https://healthy.kaiserpermanente.org/health-wellness/health-encyclopedia/he.colic-harmful-treatments.hw31230> (last visited Nov. 29, 2022).

1 81. As described herein, the Product’s implied advertising message violates the FDCA
2 because it is misleading and implies disease prevention and treatment. Thus, the GRAS status is not
3 applicable and is not a preemption defense.

4 82. Further, GRAS status only applies to “a component of food . . . under the conditions
5 of its intended use.” 21 C.F.R. § 170.35. Here, baking soda is not GRAS for disease treatment or
6 prevention.

7 83. Defendant’s Product is not approved by the FDA or any other regulatory agency for
8 use in newborns and infants experiencing the symptoms of colic. Walmart also fails to comply with
9 over-the-counter drug regulations for antacids and, thus, is not a legal over-the-counter antacid (*see*
10 by 21 C.F.R. §§ 201.66(c), 331, § 331.11(k)(1)).

11 84. Walmart’s Gripe Water is not a food and, instead, is advertised by Walmart as a
12 medicine to treat infants and newborns suffering from the symptoms of colic. The intended use of
13 the product has not been approved by the FDA, and the evidence has found that baking soda (along
14 with the herbal ingredients in Walmart’s Gripe Water) is ineffective and can only disrupt an infant’s
15 and newborn’s digestive system. A Product that disrupts the digestive system does not help with the
16 symptoms of colic.

17 **THE IMPACT OF DEFENDANT’S WRONGFUL CONDUCT**

18 85. Defendant has ignored California law, federal regulations, and the scientific evidence
19 demonstrating Parent’s Choice Gripe Water ineffectiveness. It has conveyed and continues to
20 convey that Parent’s Choice Gripe Water is a “dietary supplement” (it is not because Defendant
21 does not comply with the regulations) capable of benefiting the symptoms of colic (it does not).

22 86. As the manufacturer and distributor of Parent’s Choice Gripe Water, Defendant
23 possesses specialized knowledge regarding its content and effects of its ingredients, and Defendant
24 is in a superior position to know whether Parent’s Choice Gripe Water works as advertised.

25 87. Specifically, Defendant knew, but failed to disclose, or should have known, that
26 Parent’s Choice Gripe Water is a product that is unlawfully sold and cannot benefit the symptoms
27 of colic.
28

1 88. Defendant knew, but failed to disclose, or should have known, that Parent's Choice
2 Gripe Water is ineffective at relieving the symptoms of colic because the evidence-based science
3 has determined that Parent's Choice Gripe Water does not relieve the signs and symptoms of colic.

4 89. Plaintiff and the Class members have been and will continue to be deceived or misled
5 by Defendant's false and deceptive colic-relief representations.

6 90. Defendant's colic-relief representations and omissions were a material factor in
7 influencing Plaintiff's and the class members' decision to purchase Parent's Choice Gripe Water.
8 In fact, the only purpose for purchasing Parent's Choice Gripe Water is to obtain the promised colic-
9 relief benefits. Defendant's conduct has injured Plaintiff and the class members because Parent's
10 Choice Gripe Water does not provide the advertised benefits. Had Plaintiff and other reasonable
11 consumers known this, they would not have purchased Parent's Choice Gripe Water or would not
12 have paid the prices they paid. Furthermore, had Plaintiff and other reasonable consumers known
13 that Parent's Choice Gripe Water is not a dietary supplement and cannot be legally sold, they would
14 not have purchased Parent's Choice Gripe Water or would not have paid the prices they paid.

15 91. Parent's Choice Gripe Water retails for approximately \$6 per unit. Because of
16 Defendant's unlawful, false, and deceptive advertising, Parent's Choice Gripe Water has become
17 one of the highest-selling products in the gripe water category.

18 **LEGAL REMEDIES ARE INADEQUATE**

19 92. Plaintiff and members of the Class are entitled to equitable relief as no adequate
20 remedy at law exists. The statutes of limitations for the causes of action pled herein vary. Class
21 members who purchased the Product more than three years prior to the filing of the complaint will
22 be barred from recovery if equitable relief were not permitted under the UCL.

23 93. The scope of actionable misconduct under the unfair prong of the UCL is broader than
24 the other causes of action asserted herein. It includes Defendant's overall unfair marketing scheme
25 to promote and brand the Product with the labeling representations, across a multitude of media
26 platforms, including the Product's labels and packaging, over a long period of time, in order to gain
27 an unfair advantage over competitor products. The UCL also creates a cause of action for violations
28

1 of law (such as statutory or regulatory requirements and court orders related to similar
2 representations and omissions made on the type of products at issue). This is especially important
3 here because Plaintiff alleges Defendant has committed “unlawful” acts by failing to comply with
4 21 U.S.C. §§ 343(r)(6), 21 U.S.C. § 343(a), 21 C.F.R. § 1.21(a), 21 C.F.R. § 101.93(g), 21 C.F.R. §
5 101.93(a)-(b), and Cal. Health & Saf. Code §§ 110100, 111550 (*see also* below Count II) and brings
6 a claim for violation of the UCL’s “unlawful prong.” No other causes of action allow this claim to
7 proceed, and thus, there is no adequate remedy at law for this specific violation of the UCL’s
8 unlawful prong. Plaintiff’s UCL unlawful prong claim does not rest on the same conduct as his other
9 causes of action, and there is no adequate remedy at law for this specific claim.

10 94. Injunctive relief is appropriate on behalf of Plaintiff and members of the Class because
11 Defendant continues to misrepresent the Products with the colic relief and other “gripe water”
12 representations and violate federal and state regulations. Injunctive relief is necessary to prevent
13 Defendant from continuing to engage in the unfair, fraudulent, and/or unlawful conduct described
14 herein and to prevent future harm—none of which can be achieved through available legal remedies
15 (such as monetary damages to compensate past harm). Injunctive relief, in the form of affirmative
16 disclosures is necessary to dispel the public misperception about the Products that has resulted from
17 years of Defendant’s unfair, fraudulent, and unlawful marketing efforts. Such disclosures would
18 include, but are not limited to, publicly disseminated statements that the Products’ labeling
19 misrepresentations are not true and providing accurate information about the Products’ true nature;
20 and/or requiring prominent qualifications and/or disclaimers on the Products’ front label concerning
21 the Products’ true nature. An injunction requiring affirmative disclosures to dispel the public’s
22 misperception, and prevent the ongoing deception and repeat purchases, is also not available through
23 a legal remedy (such as monetary damages). In addition, Plaintiff is currently unable to accurately
24 quantify the damages caused by Defendant’s future harm, because discovery and Plaintiff’s
25 investigation have not yet completed, rendering injunctive relief necessary. Further, because a
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1 public injunction is available under the UCL, and damages will not adequately benefit the general
2 public in a manner equivalent to an injunction.

3 95. It is premature to determine whether an adequate remedy at law exists. This is an
4 initial pleading and discovery has not yet commenced and/or is at its initial stages. No class has
5 been certified yet. No expert discovery has commenced and/or completed. The completion of
6 fact/non-expert and expert discovery, as well as the certification of this case as a class action, are
7 necessary to finalize and determine the adequacy and availability of all remedies, including legal
8 and equitable, for Plaintiff's individual claims and any certified class or subclass. Plaintiff therefore
9 reserves their right to amend this complaint and/or assert additional facts that demonstrate this
10 Court's jurisdiction to order equitable remedies where no adequate legal remedies are available for
11 either Plaintiff and/or any certified class or subclass. Such proof, to the extent necessary, will be
12 presented prior to the trial of any equitable claims for relief and/or the entry of an order granting
13 equitable relief.

14 **CLASS ACTION ALLEGATIONS**

15 96. Plaintiff brings this class action pursuant to Federal Rules of Civil Procedure 23(b)(2)
16 and 23(b)(3) on behalf of the following classes:

17 **Multi-State Unjust Enrichment Class (the "Class")**

18 All persons who purchased Parent's Choice Gripe Water for personal use in
19 California or other states with similar laws until the date notice is disseminated.

20 **California Class (the "Subclass")**

21 All persons in California who purchased Parent's Choice Gripe Water for
22 personal use until the date notice is disseminated.

23 97. Together the classes are referred to as the "Class" below. Excluded from the from the
24 Class are: (i) Defendant and its officers, directors, and employees; (ii) any person who files a valid
25 and timely request for exclusion; and (iii) judicial officers and their immediate family members and
26 associated court staff assigned to the case.

1 98. Plaintiff reserves the right to amend or otherwise alter the class definition presented
2 to the Court at the appropriate time, or to propose or eliminate sub-classes, in response to facts
3 learned through discovery, legal arguments advanced by Defendant, or otherwise.

4 99. The Class is appropriate for certification because Plaintiff can prove the elements of
5 the claims on a classwide basis using the same evidence as would be used to prove those elements
6 in individual actions alleging the same claims.

7 100. Numerosity: Class Members are so numerous that joinder of all members is
8 impracticable. Plaintiff believes that there are thousands of consumers who are Class Members
9 described above who have been damaged by Defendant's deceptive and misleading practices.

10 101. Commonality and Predominance: There is a well-defined community of interest in the
11 common questions of law and fact affecting all Class Members. The questions of law and fact
12 common to the Class Members which predominate over any questions which may affect individual
13 Class Members include, but are not limited to:

- 14 a. Whether Defendant is responsible for the conduct alleged herein which was uniformly
15 directed at all consumers who purchased the Products;
16 b. Whether Defendant's misconduct set forth in this Complaint demonstrates that
17 Defendant engaged in unfair, fraudulent, or unlawful business practices with
18 respect to the advertising, marketing, and sale of the Products;
19 c. Whether Defendant made false and/or misleading statements concerning the Products
20 that were likely to deceive the public;
21 d. Whether Plaintiff and the Class are entitled to injunctive relief;
22 e. Whether Plaintiff and the Class are entitled to money damages under the same causes
23 of action as the other Class Members.

24 102. Typicality: Plaintiff is a member of the Class Plaintiff seeks to represent. Plaintiff's
25 claims are typical of the claims of each Class Member in that every member of the Class was
26 susceptible to the same deceptive, misleading conduct and purchased the Products. Plaintiff is
27 entitled to relief under the same causes of action as the other Class Members.
28

1 103. Adequacy: Plaintiff is an adequate Class representative because Plaintiff's interests
2 do not conflict with the interests of the Class Members Plaintiff seeks to represent; the consumer
3 fraud claims are common to all other members of the Class, and Plaintiff has a strong interest in
4 vindicating Plaintiff's rights; Plaintiff has retained counsel competent and experienced in complex
5 class action litigation and Plaintiff intends to vigorously prosecute this action. Plaintiff has no
6 interests which conflict with those of the Class. The Class Members' interests will be fairly and
7 adequately protected by Plaintiff and proposed Class Counsel. Defendant has acted in a manner
8 generally applicable to the Class, making relief appropriate with respect to Plaintiff and the Class
9 Members. The prosecution of separate actions by individual Class Members would create a risk of
10 inconsistent and varying adjudications.

11 104. Superiority: The Class is properly brought and should be maintained as a class action
12 because a class action is superior to traditional litigation of this controversy. A class action is
13 superior to the other available methods for the fair and efficient adjudication of this controversy
14 because:

- 15 a. The joinder of hundreds of individual Class Members is impracticable, cumbersome,
16 unduly burdensome, and a waste of judicial and/or litigation resources;
 - 17 b. The individual claims of the Class Members may be relatively modest compared with
18 the expense of litigating the claim, thereby making it impracticable, unduly
19 burdensome, and expensive to justify individual actions;
 - 20 c. When Defendant's liability has been adjudicated, all Class Members' claims can be
21 determined by the Court and administered efficiently in a manner far less burdensome
22 and expensive than if it were attempted through filing, discovery, and trial of all
23 individual cases;
 - 24 d. This class action will promote orderly, efficient, expeditious, and appropriate
25 adjudication and administration of Class claims;
 - 26 e. Plaintiff knows of no difficulty to be encountered in the management of this action
27 that would preclude its maintenance as a class action;
- 28

1 f. This class action will assure uniformity of decisions among Class Members;

2 g. The Class is readily definable and prosecution of this action as a class action will
3 eliminate the possibility of repetitious litigation; and

4 h. Class Members' interests in individually controlling the prosecution of separate
5 actions is outweighed by their interest in efficient resolution by single class action;

6 105. Rule 23(b)(2): In the alternative, the Class also may be certified because Defendant
7 has acted or refused to act on grounds generally applicable to the Class thereby making final
8 declaratory and/or injunctive relief with respect to the members of the Class as a whole, appropriate.

9 106. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of
10 the Class, on grounds generally applicable to the Class, to enjoin and prevent Defendant from
11 engaging in the acts described, and to require Defendant to provide full restitution to Plaintiff and
12 Class members.

13 107. Unless the Class is certified, Defendant will retain monies that were taken from
14 Plaintiff and Class members as a result of Defendant's wrongful conduct. Unless a classwide
15 injunction is issued, Defendant will continue to commit the violations alleged and the members of
16 the Class and the general public will continue to be misled.

17 108. Notice: Plaintiff and counsel anticipate that notice to the proposed Class will be
18 effectuated through recognized, Court-approved notice dissemination methods, which may include
19 United States mail, electronic mail, Internet postings, and/or published notice.

20 **COUNT I**

21 **Violation of Consumer Legal Remedies Act ("CLRA")** 22 **Civil Code §§ 1750, *et seq***

23 109. Plaintiff re-alleges and incorporates by reference all allegations set forth in the
24 preceding paragraphs as if fully set forth verbatim herein.

25 110. Plaintiff brings this claim individually and on behalf of the California Subclass against
26 Defendant.

27 111. At all times relevant hereto, Plaintiff and members of the Class were "consumer[s],"
28 as defined in Civil Code section 1761(d).

1 112. At all relevant times, Defendant constituted a “person,” as defined in Civil Code
2 section 1761(c).

3 113. At all relevant times, the Products manufactured, marketed, advertised, and sold by
4 Defendant constituted “goods,” as defined in Civil Code section 1761(a).

5 114. The purchases of the Products by Plaintiff and members of the Class were and are
6 “transactions” within the meaning of Civil Code section 1761(e).

7 115. Defendant disseminated, or caused to be disseminated, through its advertising—
8 including Defendant’s Website Claims that the Products are a treatment to the flu and the symptoms
9 of colic and are lawfully sold in the United States which they are not because the Products do not
10 provide relief from the flu, the symptoms of colic, and are illegal unapproved drugs. Defendant’s
11 representations violate the CLRA by:

- 12 (a) Defendant represented that the Products have characteristics, ingredients, uses, and
13 benefits which they do not have (Civil Code § 1770(a)(5));
- 14 (b) Defendant represented that the Products are of a particular standard, quality, or grade,
15 which they are not (Civil Code § 1770(a)(7));
- 16 (c) Defendant advertised the Products with an intent not to sell the Products as advertised
17 (Civil Code § 1770(a)(9)); and
- 18 (d) Defendant represented that the subject of a transaction has been supplied in
19 accordance with a previous representation when it has not (Civil Code § 1770(a)(16)).

20 116. Defendant violated the CLRA because the Products do not relieve the symptoms of
21 colic (e.g., stomach discomfort, gassiness). Defendant knew or should have known that its Products
22 do not relieve the symptoms of colic and that the labeling is illegal.

23 117. Defendant’s actions as described herein were done with conscious disregard of
24 Plaintiff’s rights and was wanton and malicious.

25 118. Defendant’s wrongful business practices constituted, and constitute, a continuing
26 course of conduct in violation of the CLRA since Defendant is still representing that its Products
27 have characteristics which they do not have.
28

119. Pursuant to Civil Code section 1782(d), Plaintiff and members of the Class seek an order enjoining Defendant from engaging in the methods, acts, and practices alleged herein, and for restitution and disgorgement.

120. Pursuant to Civil Code section 1782, on November 30, 2022, Plaintiff notified Defendant in writing by certified mail of the alleged violations of the CLRA and demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. Defendant has failed to rectify or agree to rectify the problems associated with the actions detailed herein and give notice to all affected consumers within 30 days of the date of written notice pursuant to § 1782 of the CLRA. Thus, Plaintiff seeks claims for actual, punitive, and statutory damages, as appropriate.

121. Pursuant to § 1780(d) of the CLRA, attached as **Exhibit 2** is an affidavit showing that this action was commenced in a proper forum.

COUNT II

Violation of Unfair Competition Law Business & Professional Code §§ 17200, *et seq.*

122. Plaintiff and Class Members reallege and incorporate by reference each allegation set forth above as if fully set forth herein.

123. Plaintiff brings this claim individually and on behalf of members of the California Subclass against Defendant.

124. Defendant is subject to the UCL, Bus. & Prof. Code § 17200 *et seq.* The UCL provides, in pertinent part: “Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising” The UCL also provides for injunctive relief and restitution for violations.

125. “By proscribing any unlawful business practice, § 17200 borrows violations of other laws and treats them as unlawful practices that the UCL makes independently actionable.” *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999) (citations and internal quotation marks omitted).

126. Virtually any law or regulation—federal or state, statutory, or common law—can

1 serve as a predicate for a UCL “unlawful” violation. *Klein v. Chevron U.S.A., Inc.*, 202 Cal. App.
2 4th 1342, 1383 (2012).

3 127. Defendant has violated the UCL’s “unlawful prong” as a result of its violations of the
4 CLRA and numerous state and federal laws governing drugs and dietary supplements. By failing to
5 comply federal and state regulations governing drugs and dietary supplements, Defendant has also
6 violated 21 U.S.C. §§ 343(r)(6), 21 U.S.C. § 343(a), 21 C.F.R. § 1.21(a), 21 C.F.R. §101.93(g), 21
7 C.F.R. § 101.93(a)-(b), and Cal. Health & Saf. Code §§ 110100, 111550.

8 a. 21 U.S.C. §§ 343(r)(6): Defendant violates this law because the advertising is
9 misleading (21 U.S.C. §§ 343(r)(6)(B)), the label does not contain the FDA required
10 disclaimer (21 U.S.C. §§ 343(r)(6)(C)), and Defendant did not send the U.S. Secretary
11 of Health and Human Services a notice of the labeling statements within 30 days after
12 first marketing the Product (21 U.S.C. §§ 343(r)(6)(C)).

13 b. 21 U.S.C. § 343(a): Defendant violates this law because the Product’s labeling is
14 misleading which also violates “section 350(b)(2) of this title.”

15 c. 21 C.F.R. § 1.21(a): Defendant violates this law because the Product’s labeling is
16 misleading as it fails to reveal facts that are (1) material in light of other representation
17 made or suggested by statement, word, design, devise or an combination thereof; and
18 (2) material with respect to consequences which may result from use of the Product
19 under the condition prescribed in the labeling and conditions of use as are customary
20 and/or usual.

21 d. 21 CFR §101.93(g): Defendant violates this law because, as described herein, the
22 Product’s labeling implies the product mitigates, treats cures, or prevents disease
23 under 21 U.S.C. § 343(r)(6).

24 e. 21 C.F.R. § 101.93(a): Defendant violates this law because it did not send the U.S.
25 Secretary of Health and Human Services a notice of the labeling statements within 30
26 days after first marketing the Product.

27 f. 21 C.F.R. § 101.93(b): Defendant violates this law because the Product’s label does
28

not contain the FDA required disclaimer.

g. Cal. Health & Saf. Code § 110100: Defendant violates this law because defendant violates food and dietary supplement regulations (as described above and throughout) under the Federal Food, Drug, and Cosmetic Act.

h. Cal. Health & Saf. Code § 111550: Defendant violates this law because it is selling an unapproved drug as defined by the Federal Food, Drug, and Cosmetic Act and as the Federal Food, Drug, and Cosmetic Act is interpreted by case law including *Kroessler v. CVS Health Corp.*, 977 F.3d 803 (9th Cir. 2020).

128. Throughout the Class Period, Defendant committed acts of unfair competition, as defined by § 17200, by using unlawful and misleading statements to promote the sale of the Products, as described above.

129. Defendant's misrepresentations and other conduct, described herein, violated the "unfair prong" of the UCL because the conduct is substantially injurious to consumers, offends public policy, and is immoral, unethical, oppressive, and unscrupulous, as the gravity of the conduct outweighs any alleged benefits. Defendant's conduct is unfair in that the harm to Plaintiff and members of the California Subclass arising from Defendant's conduct outweighs the utility, if any, of those practices.

130. Defendant's practices as described herein are of no benefit to consumers who are tricked into believing that the Products will provide relief for stomach discomfort for their newborns. Defendant's practice of injecting misinformation into the marketplace about the capabilities of its Products is unethical and unscrupulous, especially because consumers trust companies like Defendant to provide accurate information about Products for newborns. Taking advantage of that trust, Defendant misrepresents the effectiveness of its Products to increase its sales. Consumers believe that Defendant is an authority on the effectiveness, safety and quality of gripe water Products for their newborns and therefore believe Defendant's representations that its Products can provide stomach relief for their newborns/infants.

131. Defendant's conduct described herein, violated the "fraudulent" prong of the UCL by

1 representing that the Products were effective at providing relief related for stomach discomfort in
2 newborns, when in fact they were not.

3 132. Plaintiff and members of the California Subclass are not sophisticated experts with
4 independent knowledge of the formulations or efficacy of the Products, and they acted reasonably
5 when they purchased the Products based on their belief that Defendant's representations were true.

6 133. Defendant knew or should have known, through the exercise of reasonable care, that
7 its representations about the Products were untrue and misleading.

8 134. As a direct and proximate result of these acts, consumers have been and are being
9 harmed. Plaintiff and members of the California Subclass have suffered injury and actual out of
10 pocket losses as a result of Defendant's unfair, unlawful, and fraudulent business acts and practices
11 because: (a) Plaintiff and members of the California Subclass would not have purchased the
12 Products on the same terms if they had known the true facts regarding the lack of effectiveness of
13 the Products; (b) Plaintiff and members of the California Subclass paid a price premium due to the
14 misrepresentations of Defendant's Products; and (c) Defendant's Products did not have the quality,
15 effectiveness, or value as promised.

16 135. Pursuant to California Business & Professions Code § 17203, Plaintiff and members
17 of the California Subclass are therefore entitled to: (a) an Order requiring Defendant to cease the
18 acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendant as a
19 result of its deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment
20 of Plaintiff's attorneys' fees and costs.

21 **COUNT III**

22 **Unjust Enrichment**

23 136. Plaintiff and Class Members reallege and incorporate by reference each allegation set
24 forth above as if fully set forth herein.

25 137. Plaintiff brings this claim individually and on behalf of the members of the Class
26 against Defendant.
27
28

1 138. Plaintiff and Class members conferred a benefit on Defendant by purchasing the
2 Products and by paying a price premium for them. Defendant has knowledge of such benefits.

3 139. Defendant has been unjustly enriched in retaining the revenues derived from Class
4 members' purchases of the Products, which retention under these circumstances is unjust and
5 inequitable because Defendant misrepresented that the Products were effective in treating stomach
6 discomfort and colic. This misrepresentation cause injuries to Plaintiff and Class Members, because
7 they would not have purchased the Products if the true facts regarding the effectiveness of the
8 Products were known.

9 140. Because Defendant's retention of the non-gratuitous benefit conferred on it by
10 Plaintiff and Class members is unjust and inequitable, Defendant must pay restitution to Plaintiff
11 and the Class members for their unjust enrichment, as ordered by the Court.

12 **JURY DEMAND**

13 141. Plaintiff demands a trial by jury on all issues so triable.

14 **REQUEST FOR RELIEF**

15 WHEREFORE, Plaintiff, individually and on behalf of the Class and Subclass, requests for
16 judgment as follows:

17 (a) Declaring this action to be a proper class action and certifying Plaintiff as the
18 representative of the Class and the California Subclass, and Plaintiff's attorneys as Class Counsel
19 to represent the Class and California Subclass members;

20 (b) An order declaring Defendant's conduct violates the statutes referenced herein;

21 (c) Entering preliminary and permanent injunctive relief against Defendant, directing
22 Defendant to correct its practices and to comply with consumer protection statutes;

23 (d) Awarding damages, including treble damages

24 (e) Awarding punitive damages;

25 (f) Awarding restitution and disgorgement in the alternative to damages in an amount that is
26 different than the amount that would be compensable for damages;

1 (g) Awarding Plaintiff and the Class and the California Subclass Members their costs and
2 expenses incurred in this action, including reasonable allowance of fees for Plaintiff's attorneys and
3 experts, and reimbursement of Plaintiff's expenses; and

4 (h) Granting such other and further relief as the Court may deem just and proper.

5 Dated: June 15, 2023

CROSNER LEGAL, P.C.

6 By: /s/ Craig W. Straub
7 Craig W. Straub
8 Zachary M. Crosner
9 Chad A. Saunders

Attorneys for Plaintiff